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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,428	08/14/2006	Patrice Richard	Q94528	4756

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
EISEMAN, ADAM JARED	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,428	RICHARD ET AL.	
	Examiner	Art Unit	
	ADAM J. EISEMAN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/27/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on October 30, 2003. It is noted, however, that applicant has not filed a certified copy of the French application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 4/27/2006 was received and placed in the record on file. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject

matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation.

There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

3. The spacing of the lines of the specification is such as to make reading difficult. New application papers with lines 1½ or double spaced on good quality paper are required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13-14, 17-18, and 22 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 13-14 and 18 recite the limitations "inlet port", “outlet port”, and “mixing chamber” in describing the system for extracting bone marrow. There is insufficient antecedent basis for these limitations in the claims since the inlet port, outlet port, and mixing chamber are not limitations of claim 11 (or claim 1, which claim 11 is dependent

upon). The lack of antecedent basis could be overcome by making claim 11 dependent on claim 12 instead of claim 11; or by amending the preamble for claims 13-14 and 18 to recite dependency on claim 7, for example: "a bone marrow extraction system characterized in that it includes a device according to claim 1, comprising:". For examination purposes the examiner will assume that the applicant intended claims 13-14, and 18 to recite dependency on claim 7.

7. Regarding claims 17 and 22, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-4, 11, 15-17, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton (US 7,179,232) in view of Twersky (US 4,445,788).

Sutton discloses a bone marrow extraction device comprising:

- A grip zone (element 52)
- A needle (element 24) presenting at least one side orifice (element 26)
- The device characterized in that the needle is connected to a needle holder (enlarged proximal portion of inner needle; figure 3), and in that a protective sleeve (outer cannula, element 16) surrounds at least a part of said needle (see figure 1-3), said protective sleeve being mounted to move relative to said needle between a closed position the side orifice and an open position of the side orifice (column 5, lines 16-28)
- A mating arrangement between the needle holder and the base of the sheath to connect the inner and outer cannula and permit rotational movement of the cannula so as to selectively align the orifices of the cannula between the open and closed position (column 4, line 56 to column 5, line 9)

However, Sutton does not disclose fastener means on the protective sleeve to engage reception means on the needle holder so as to hold the protective sleeve in the open or closed position.

Twersky teaches the use of a detent mechanism (element 29) used to lock a sheath into either an open position where apertures in the sheath aligned with inner apertures or to a closed position where the sheath shields the apertures (column 3, lines 9-21).

Regarding claims 1-4, 11, and 15-17; Sutton teaches the use of indicia (elements 58) on the sheath handle and needle holder which place the apertures in an open position when aligned and a closed position when misaligned (column 6, lines 48-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Sutton to use a locking/fastening mechanism as taught by Twersky for holding the sheath and needle apertures in an open or closed position in order to provide the user with the ability to quickly and assuredly move the orifice between the open and closed positions.

Further regarding claim 2; Sutton discloses that the outer cannula is mounted to turn about the inner cannula.

Further regarding claim 3; Sutton discloses that the sheath includes at least one side opening (element 20) that is positioned facing the orifice of the needle in the open position (column 5, lines 16-28).

Further regarding claim 4; Sutton discloses that the handle part of the sheath (element 32) is used for mating the sheath to the needle.

Further regarding claim 11 and 15-16; Sutton discloses that the device can be used to extract bone marrow.

Further regarding claims 15-17; Sutton discloses an outlet port (element 54) connected to the needle for connection to any well known medical device for providing suction (column 6, lines 40-47). Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a vacuum pump as the suction

means as they are a well known device for providing suction and that pedals are well known actuators for actuating medical devices.

Further regarding claim 23; it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device in sterile packaging as it is well known in the art of medical devices to use sterile packaging to prevent infection and disease.

11. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton in view of Twersky as applied to claim 4 above, and further in view of Juhn (US 4,641,663).

The Sutton/Twersky combination is described in the rejection of claims 4 above; however it does not disclose that the fastener means are a pivotally mounted claw that presents a manual actuation surface and projection.

Juhn discloses a fastening means that is a pivotally mounted claw-like fastener (element 67) that presents an actuation surface (element 74) and a projection (element 73) which locks an inner cannula into a position (figures 5-8).

Regarding claims 5-6; it would have been obvious to one of ordinary skill in the arts at the time of the invention to substitute the fastening/locking means of the Sutton/Twersky combination with Juhn's claw fastening mean in order to provide an actuation surface for easier connection and locking.

Further regarding claim 6; it would have been obvious to one of ordinary skill in the art that the use of Juhn's locking means requires a groove or ledge for receiving the projection (element 73) in order for the fastening means to hold.

12. Claims 7-10 and 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton in view of Twersky as applied to claim 1 and 11 above, and further in view of Shapira (US 6,110,176).

The Sutton/Twersky combination is described in the rejection of claims 1 and 11 above; however it does not disclose a mixing chamber with an inlet and outlet port; providing an anticoagulant to the inlet channel; or connecting the outlet channel to a bone marrow collection vessel.

Shapira teaches a system and method for extracting bone marrow comprising: extracting bone marrow using the bone marrow extraction needle (element 85); mixing the extracted bone marrow with an anticoagulant solution; and transferring the mixed bone marrow solution to a collection chamber (column 8, lines 40-59). Furthermore, Shapira teaches that the solution can be mixed with the bone marrow before being transferred to the collecting means (column 8, lines 54-59).

Regarding claims 7-10 and 12-19; Shapira teaches the method of extracting bone marrow, mixing a solution with bone marrow, and transferring the mixed solution to a collection chamber but does not disclose the specifics of the apparatus used to perform extraction/mixing operation. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the Sutton/Twersky combination as the bone marrow extraction needle used in the method as taught by Shapira as simple substitution of one known element with another.

Further regarding claim 7-10 and 12-19; it would have been obvious to one of ordinary skill in the art at the time of the invention to include a mixing chamber where

mixing occurs having an inlet port for the infused solution and an outlet port for transferring the mixed bone marrow/infusion solution to the collection chamber. Furthermore, it would have been obvious to one of ordinary skill in the art to include this mixing chamber anywhere in fluid communication with the biopsy site and collection chamber but before the collection chamber, including in the needle holder, in the handle, or as an insert to the Sutton/Twersky bone marrow extraction needle. It would have been obvious to try as choosing from a finite number of predictable solutions with reasonable expectation of success.

Further regarding claim 13; Shapira discloses use of an anticoagulant infused into the bone marrow mixing chamber. It would have been obvious to one of ordinary skill in the art that this would use an inlet channel.

Further regarding claim 14; Shapira disclose extracting the mixed bone marrow to a collection chamber. It would have been obvious to one of ordinary skill in the art that this would use an outlet channel.

Further regarding claim 15-17 and 19; Shapira discloses use of suction means to extract the bone marrow from the extraction site to the collection chamber. It would have been obvious to one of ordinary skill in the art a the time of the invention to use any well known suction means for providing suction to the needle including vacuum pumps, pedal actuated pumps, and timed pumps.

Further regarding claim 18; it would have been obvious to one of ordinary skill in the art at the time of the invention to use the inlet valve to project the infused fluid into

the mixing chamber towards the outlet channel to create the Venturi effect and promote mixing.

13. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton in view of Twersky as applied to claim 1 above, and further in view of Morawski (US 2004/0010236).

The Sutton/Twersky combination is described in the rejection of claim 1 above; however it only discloses the use of the device for the extraction of bone marrow.

Morawski teaches that although a device is described as a bone marrow aspiration device, one of ordinary skill could use an aspiration needle to inject a fluid (abstract).

Regarding claims 20-22; it would have been obvious to one of ordinary skill in the art at the time of the invention to use the Sutton/Twersky combination to inject bone marrow into a patient as taught by Morawski.

Further regarding claim 21-22; Sutton discloses that the needle can be connected to a medical syringe or similar medical device. It would have been obvious to one of ordinary skill in the art at the time of the invention that the syringe could be filled with bone marrow, thus acting as a bone marrow reservoir, and that the syringe could be electrically driven as automatic syringe drivers are well known in the art.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2004/0249306 to Islam; discloses a bone marrow biopsy needle.

US 2002/0042581 to Cervi; discloses a biopsy needle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM J. EISEMAN whose telephone number is (571)270-3818. The examiner can normally be reached on Mon-Thurs, 8:00 PM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AE
12/20/2008
/A. J. E./

Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736